Attorney's Docket No. 5470-250DV PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: R. Boucher
Serial No.: To Be Assigned
Filed: Concurrently Herewith

For: *COMPOUNDS AND METHODS FOR THE TREATMENT OF AIRWAY DISEASES AND FOR THE DELIVERY OF AIRWAY DRUGS*

March 1, 2002

BOX PATENT APPLICATION
Commissioner for Patents
Washington, DC 20231

Preliminary Amendment

Dear Sir:

In the specification:

Please delete the first paragraph entitled "Statement of Priority" and insert the following paragraph:

--STATEMENT OF PRIORITY

This application is a divisional of United States Patent Application Serial No. 09/465,429, filed December 21, 1999, which claims priority from U.S. Provisional Patent Application Serial No. 60/137,991 filed June 7, 1999 and from U.S. Provisional Patent Application Serial No. 60/113,785 filed December 22, 1998, the disclosures of which are to be incorporated by reference herein in their entirety.--

In the claims:

Please cancel claims 2-13, and 22-30, without prejudice or disclaimer.

Please amend the following claim:

1 (amended). A method for treating chronic obstructive pulmonary disease in a subject in need of such treatment, comprising administering at least one osmotically active compound to an airway surface of the subject in an amount effective to increase the volume of liquid on the airway surface;

wherein the at least one osmotically active compound comprises at least one salt.

Please add the following claims:

31 (new). A method according to claim 1, wherein said at least one salt comprises an anion selected from the group consisting of acetate, benzenesulfonate, benzoate, bicarbonate, bitartrate, bromide, calcium edetate, camsylate, carbonate, chloride, citrate, dihydrochloride, edetate, edisylate, estolate, esylate, fumarate, gluceptate, gluconate, glutamate, glycollylarsanilate, hexylresorcinate, hydrabamine, hydrobromide, hydrochloride, hydroxynaphthoate, iodide, isethionate, lactate, lactobionate, malate, maleate, mandelate, mesylate, methylbromide, methylnitrate, methylsulfate, mucate, napsylate, nitrate, pamoate, pantothenate, phosphate or diphosphate, polygalacturonate, salicylate, stearate, subacetate, succinate, sulfate, tannate, tartrate, teoclate, triethiodide, and bicarbonate,

32 (new). A method according to claim 1, wherein said at least one salt comprises an anion selected from the group consisting of sulfate, nitrate, gluconate, iodide, bicarbonate, bromide, and phosphate.

33 (new). A method according to claim 1, wherein said at least one salt comprises a cation selected from the group consisting of benzathine , chloroprocaine, choline, diethanolamine, ethylenediamine, meglumine, procaine, D-Lysine, L-lysine, D-arginine, L-arginine, triethylammonium, N-methyl D-glycerol, aluminum, calcium, lithium, magnesium, potassium, sodium, zinc, iron, and ammonium.

34 (new). The method according to claim 1, wherein said at least one salt comprises a cation selected from the group consisting of choline, lithium, meglumine, D-lysine, ammonium, magnesium, calcium, and potassium.

35 (new). A method according to claim 1, wherein said at least one salt comprises:

an anion selected from the group consisting of sulfate, nitrate, gluconate, iodide, bicarbonate, bromide, and phosphate; and

a cation selected from the group consisting of choline, lithium, meglumine, D-lysine, ammonium, magnesium, calcium, and potassium.

36 (new). A method according to claim 1, wherein said at least one salt comprises a single salt.

37 (new). A method according to claim 1, wherein said at least one salt comprises a combination of different salts.

38 (new). A method according to claim 37, wherein said different salts have a same anion.

39 (new). A method according to claim 37, wherein said different salts have a same cation.

40 (new). A method according to claim 37, wherein said salt comprises an anion and a cation, and wherein at least one of said anion and said cation are non-absorbable in relation to said airway surface.

41 (new). A method according to claim 37, wherein said salt comprises an anion and a cation, and wherein both of said anion and said cation are non-absorbable in relation to said airway surface.

42 (new). A method according to claim 1, wherein said at least one salt is selected from the group consisting of:

choline chloride, choline iodide, lithium chloride, meglumine chloride, L-lysine chloride, D-lysine chloride, ammonium chloride, potassium sulfate, potassium nitrate,

potassium gluconate, potassium iodide, ferric chloride, ferrous chloride, potassium bromide,potassium phosphate, potassium bicarbonate, and sodium bicarbonate.

43 (new). A method according to claim 1, wherein said at least one salt is selected from the group consisting of:

potassium sulfate, potassium nitrate, potassium gluconate, potassium iodide, potassium bromide, potassium phosphate, and potassium bicarbonate.

44 (new). A method according to claim 1, wherein said at least one salt is potassium sulfate, potassium nitrate, potassium gluconate, potassium iodide, potassium bromide, potassium phosphate, and potassium bicarbonate.

45 (new). A method according to claim 1, wherein said at least one salt is potassium nitrate.

46 (new). A method according to claim 1, wherein said at least one salt is potassium gluconate.

47 (new). A method according to claim 1, wherein said at least one salt is potassium iodide.

48 (new). A method according to claim 1, wherein said at least one salt is potassium bromide.

49 (new). A method according to claim 1, wherein said at least one salt is potassium phosphate.

50 (new). A method according to claim 1, wherein said at least one salt is potassium bicarbonate.

Remarks

This is in response to the Restriction Requirement of March 23, 2001, in the parent of the instant application, in which the claims were restricted into group I (claims 1-21), group II (claims 22-29) and group III (claim 30). Group II having been chosen in the parent case, this case is filed to pursue group I, and claims to the non-elected groups are cancelled herein, without prejudice or disclaimer.

In addition, claims 2-13 have been cancelled, either for the purpose of rewriting or simplifying the issues, to focus on ionic osmolytes, specifically salts.

Claim 1 has been amended to incorporate claims 2-3 and to recite "at least one" salt, support for which is found in the specification at page 5 line 25 ("either a single salt or a combination of different salts may be used").

The newly added claims to particular anions, cations, and combinations of different salts are supported by the specification at page 4 line 15 to page 5 line 28.

It is respectfully submitted that this application is in condition for substantive examination, which action is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made"**

Respectfully submitted,

Kenneth D. Sibley
Registration No. 31,665

CERTIFICATE OF EXPRESS MAILING

Express Mail Label No. EV015808859US
Date of Deposit: March 1, 2002

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: BOX PATENT APPLICATION, Commissioner for Patents, Washington, DC 20231.

Vickie Diane Prior

Version with Markings to Show Changes Made

1 (amended). A method for treating chronic obstructive pulmonary disease in a subject in need of such treatment, comprising administering [an] at least one osmotically active compound to an airway surface of the subject in an amount effective to increase the volume of liquid on the airway surface;

wherein the at least one osmotically active compound comprises at least one salt.

31 (new). A method according to claim 1, wherein said at least one salt comprises an anion selected from the group consisting of acetate, benzenesulfonate, benzoate, bicarbonate, bitartrate, bromide, calcium edetate, camsylate, carbonate, chloride, citrate, dihydrochloride, edetate, edisylate, estolate, esylate, fumarate, gluceptate, gluconate, glutamate, glycollylarsanilate, hexylresorcinate, hydrabamine, hydrobromide, hydrochloride, hydroxynaphthoate, iodide, isethionate, lactate, lactobionate, malate, maleate, mandelate, mesylate, methylbromide, methylnitrate, methylsulfate, mucate, napsylate, nitrate, pamoate, pantothenate, phosphate or diphosphate, polygalacturonate, salicylate, stearate, subacetate, succinate, sulfate, tannate, tartrate, teoclate, triethiodide, and bicarbonate,

32 (new). A method according to claim 1, wherein said at least one salt comprises an anion selected from the group consisting of sulfate, nitrate, gluconate, iodide, bicarbonate, bromide, and phosphate.

33 (new). A method according to claim 1, wherein said at least one salt comprises a cation selected from the group consisting of benzathine , chloroprocaine, choline, diethanolamine, ethylenediamine, meglumine, procaine, D-Lysine, L-lysine, D-arginine, L-arginine, triethylammonium, N-methyl D-glycerol, aluminum, calcium, lithium, magnesium, potassium, sodium, zinc, iron, and ammonium.

34 (new). The method according to claim 1, wherein said at least one salt comprises a cation selected from the group consisting of choline, lithium, meglumine, D-lysine, ammonium, magnesium, calcium, and potassium.

35 (new). A method according to claim 1, wherein said at least one salt comprises:

an anion selected from the group consisting of sulfate, nitrate, gluconate, iodide, bicarbonate, bromide, and phosphate; and

a cation selected from the group consisting of choline, lithium, meglumine, D-lysine, ammonium, magnesium, calcium, and potassium.

36 (new). A method according to claim 1, wherein said at least one salt comprises a single salt.

37 (new). A method according to claim 1, wherein said at least one salt comprises a combination of different salts.

38 (new). A method according to claim 37, wherein said different salts have a same anion.

39 (new). A method according to claim 37, wherein said different salts have a same cation.

40 (new). A method according to claim 37, wherein said salt comprises an anion and a cation, and wherein at least one of said anion and said cation are non-absorbable in relation to said airway surface.

41 (new). A method according to claim 37, wherein said salt comprises an anion and a cation, and wherein both of said anion and said cation are non-absorbable in relation to said airway surface.

42 (new). A method according to claim 1, wherein said at least one salt is selected from the group consisting of:

choline chloride, choline iodide, lithium chloride, meglumine chloride, L-lysine chloride, D-lysine chloride, ammonium chloride, potassium sulfate, potassium nitrate, potassium gluconate, potassium iodide, ferric chloride, ferrous chloride, potassium bromide,potassium phosphate, potassium bicarbonate, and sodium bicarbonate.

43 (new). A method according to claim 1, wherein said at least one salt is selected from the group consisting of:

potassium sulfate, potassium nitrate, potassium gluconate, potassium iodide, potassium bromide, potassium phosphate, and potassium bicarbonate.

44 (new). A method according to claim 1, wherein said at least one salt is potassium sulfate, potassium nitrate, potassium gluconate, potassium iodide, potassium bromide, potassium phosphate, and potassium bicarbonate.

45 (new). A method according to claim 1, wherein said at least one salt is potassium nitrate.

46 (new). A method according to claim 1, wherein said at least one salt is potassium gluconate.

47 (new). A method according to claim 1, wherein said at least one salt is potassium iodide.

48 (new). A method according to claim 1, wherein said at least one salt is potassium bromide.

49 (new). A method according to claim 1, wherein said at least one salt is potassium phosphate.

50 (new). A method according to claim 1, wherein said at least one salt is potassium bicarbonate.

doc. 230914